FEB 1 0 2005

K042755

510(k) Summary

as required by 807.92

1. Company Identification

EIZO NANAO CORPORATION
153 Shimokashiwano-cho, Matto-shi, Ishikawa-ken, 924-8566, Japan
Tel: +81-76-274-2468
Fax: +81-76-274-2484

2. Official Correspondent

Hiroaki Hashimoto (Mr.)
Manager of Engineering Management Section

3. Date of Submission

October 4, 2004

4. Device Trade name

RadiForce G51, 5 Megapixel Monochrome LCD Monitor

5. Common/Usual Name:

Image display system, medical image workstation, image monitor/display, and others

6. Classification Number:

Medical displays classified in Class II per 21 CFR 892.2050.

7. Predicate Device

Manufacturer: Barco NV Barcoview
Device Name: Digital Mammography Display
Model Name: MDG 521M
510(k) No.: K033859

8. Description of Device

RadiForce G51 device is a digital image display. Clearance letter (510(k) No.: K032026, dated on AUG 27, 2003) had been issued. The device is qualified for various medical image applications including digital mammography system.

9. Intended Use

RadiForce G51 is intended to be used in various kinds of medical image applications including digital mammography system for which the device complies with the performance specified by the manufacturer of the system.

10. Substantial Equivalence to Predicate Device

RadiForce G51 is substantially equivalent to MDG 521M. G51 employs the maximum resolution values same as that of MDG 521M. Comparison table of the principal characteristics of 2 devices is shown in the Attachment 1 and specification data for the use of mammography system monitor is included in Attachment 8.

Appendix 1: Comparison Table with Predicate Device

Items	MDG 521 (Predicate Device)	RadiForce G51
510(k) Number	K033859	Not known
Panel Size and Type	21" CRT display	21.3" TFT monochrome LCD display
Picture Tube/Pixel Pitch	Faceplate transmission: 32% Phosphor: P45 (standard) or P104	0.165 mm x 0.165 mm
Available Cabinet Colors	Black	Black
Scanning Frequency (H, V)	H: 160-200kHz V: 48-150Hz	H: 103.9 kHz V: 50.06 Hz
Native Resolutions	2048 x 2560 (portrait)	2048 x 2560 (portrait) 2560 x 2048 (landscape)
Brightness	450 cd/m^2	700 cd/m^2
Contrast Ratio	2000:1	600:1
DOT Clock	500MHz pixel clock	152MHz
Input Signals	BNC	DVI Standard 1.0
Input Terminals	BNC	DVI-D 24 pin x 1
Serial Ports	1 input, 1 output 9600 baud, RS232 SUB-D9 male/female connector	D-Sub 9 pin (Remote Out), Mini DIN 6 pin (Remote In), Mini DIN 8 pin (Photo Sensor)
Active Display Size (H x V)	300 x 400 mm / 304 x 380 mm	337.9 x 422.4 mm
Dimensions (W x H x D)	558 x 400 x 561 mm	388 x 572 x 83.5 mm
Luminance Calibration	Software (Optional) Photo-sensor (Optional)	Software (Optional) Photo-sensor (Optional)
Power	AC90-264V 50-60Hz	AC100V-120V/200V-240V, 50/60Hz,
Certifications & Standards	cUL950, CE, IEC601-1, UL2601-1, cUL2601, UL1950, DIN 6868-57	TUV/GM, CE, CB, EN60601-1, UL2601-1, CSA C22.2 No. 601-1, FCC-A, Canadian ICES-003-A, VCCI-A, CCC

*Since the software used in G51 is not changed, refer to the 510(k) Summary of K32026 for the information of calibration software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 2005

Mr. Hiroaki Hashimoto
Manager of Product Safety & EMC
EIZO NANAO Corporation
153 Shimokashiwano, Matto
Ishikawa 924-8566
JAPAN

Re: K042755
Trade/Device Name: RadiForce G51
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: December 29, 2004
Received: January 3, 2005

Dear Mr. Hashimoto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

September 21, 2004

Indications for Use

510(k) Number (if known):

Device Name: RadiForce G51

Indications For Use:

5 Megapixel Monochrome LCD Monitor, RadiForce G51 is intended to be used in various kinds of medical image applications including digital mammography system for which the device complies with the performance specified by the manufacturer of the system.

Prescription Use ✓ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Lagzdins

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042755